(4) Therapeutic duplication as described in §456.705(b)(1).

(5) Drug-disease contraindication as described in §456.705(b)(2).

(6) Drug-drug interaction as described in §456.705(b)(3).

(7) Incorrect drug dosage as described in §456.705(b)(4).

(8) Incorrect duration of drug treatment as described in §456.705(b)(5).

(9) Clinical abuse or misuse as described in §456.705(b)(7).

§456.711 Educational program.

The State plan must provide for ongoing educational outreach programs that, using DUR Board data on common drug therapy problems, educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. The program may be established directly by the DUR Board or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies, or other organizations. The program must include the interventions listed in paragraphs (a) through (d) of this section. The DUR Board determines the content of education regarding common therapy problems and the circumstances in which each of the interventions is to be used.

(a) Dissemination of information to physicians and pharmacists in the State concerning the duties and powers of the DUR Board and the basis for the standards required by §456.705(c) for use in assessing drug use.

(b) Written, oral, or electronic reminders containing patient-specific or drug-specific information (or both) and suggested changes in prescribing or dispensing practices. These reminders must be conveyed in a manner designed to ensure the privacy of patient-related information.

(c) Face-to-face discussions, with follow up discussions when necessary, between health care professionals expert in appropriate drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention on optimal prescribing, dispensing, or pharmacy care practices.

(d) Intensified review or monitoring of selected prescribers or dispensers.

§456.712 Annual report.

(a) *DUR Board report.* The State must require the DUR Board to prepare and submit an annual DUR report to the Medicaid agency that contains information specified by the State.

(b) *Medicaid agency report.* The Medicaid agency must prepare and submit, on an annual basis, a report to the Secretary that incorporates the DUR Board's report and includes the following information:

(1) A description of the nature and scope of the prospective drug review program.

(2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(3) Detailed information on the specific criteria and standards in use. After the first annual report, information regarding only new or changed criteria must be provided and deleted criteria must be identified.

(4) A description of the steps taken by the State to include in the prospective and retrospective DUR program drugs dispensed to residents of a nursing facility that is not in compliance with the drug regimen review procedures set forth in part 483 of this chapter. After the first annual report, only changes must be reported.

(5) A description of the actions taken by the State Medicaid agency and the DUR Board to ensure compliance with the requirements for predetermined standards at §456.703(f) and with the access to the predetermined standards requirement at §456.703(g). After the first annual report, only changes must be reported.

(6) A description of the nature and scope of the retrospective DUR program.

(7) A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.

(8) A description of the steps taken by the State Agency to monitor compliance by pharmacies with the prospective DUR counseling requirements contained in Federal and State laws and regulations. After the first annual report, only changes must be reported.

(9) Clear statements of purpose that delineate the respective goals, objectives, and scopes of responsibility of the DUR and surveillance and utilization (SUR) functions. These statements must clarify the working relationships between DUR and SUR functions and other entities such as the Medicaid Fraud Control Unit and State Board of Pharmacy. The annual report also must include a statement delineating how functional separation will be maintained between the fraud and abuse activities and the educational activities. After the first annual report, only changes must be reported.

(10) An estimate of the cost savings generated as a result of the DUR program. This report must identify costs of DUR and savings to the Medicaid drug program attributable to prospective and retrospective DUR.

§ 456.714 DUR/surveillance and utilization review relationship.

(a) The retrospective DUR requirements in this subpart parallel a portion of the surveillance and utilization review (SUR) requirements in subpart A of this part and in part 455 of this chapter.

(b) A State agency may direct DUR staffs to limit review activities to those that focus on what constitutes appropriate and medically necessary care to avoid duplication of activities relating to fraud and abuse under the SUR program.

[59 FR 48825, Sept. 23, 1994]

§ 456.716 DUR Board.

(a) *State DUR Board requirement and member qualifications.* Each State must establish, either directly or through a contract with a private organization, a DUR Board. The DUR Board must include health care professionals who have recognized knowledge and expertise in at least one of the following:

(1) Clinically appropriate prescribing of covered outpatient drugs.

(2) Clinically appropriate dispensing and monitoring of covered outpatient drugs.

(3) Drug use review, evaluation, and intervention.

(4) Medical quality assurance.

(b) *Board composition.* At least one-third but not more than 51 percent of the DUR Board members must be physicians, and at least one-third of the Board members must be pharmacists. These physicians and pharmacists must be actively practicing and licensed.

(c) *Medicaid agency/DUR Board relationship.* The Medicaid agency is ultimately responsible for ensuring that the DUR program is operational and conforms with the requirements of this subpart. The agency has the authority to accept or reject the recommendations or decisions of the DUR Board.

(d) *DUR Board activities.* The State agency must ensure that the operational tasks involved in carrying out the DUR Board activities set forth at section 1927(g)(3)(C) of the Act are assigned, limited only by the requirements of section 1927(g)(3)(C) of the Act, based on consideration of operational requirements and on where the necessary expertise resides. Except as limited by the requirements of section 1927(g)(3)(C) of the Act, the State agency may alter the suggested working relationships set forth in this paragraph.

(1) *Application of predetermined standards: Board's activities.* The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

(ii) Evaluate the use of the predetermined standards, including assessing the operational effect of the predetermined standards in use, and make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

(iii) Recommend guidelines governing written predetermined standards that pharmacies not using approved software must use in conducting prospective DUR.

(2) *Application of predetermined standards: Medicaid agency role.* The Medicaid agency or its contractor should perform the following activities:

(i) Submit predetermined standards to the DUR Board for its review and recommendations before the Medicaid agency applies them to drug claims data.